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| EXAMINER | |
|---|---|
| IBRAHIM, MEDINA AHMED | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/016,358 | DIXON ET AL. | |
| | Examiner | Art Unit | |
| | Medina A Ibrahim | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20-33,39-46 and 52-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-33,39,40,42-46,52,54 and 55* is/are rejected.

7)☒ Claim(s) *41 and 53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 03/19/04 in reply to the Office action of 08/12/03 has been entered. Claims 1-19 and 47-51 have been cancelled. Claims 52-55 have been added. Therefore, claims 20-46 and 52-55 are pending and are examined.

The Office action contains NEW GROUNDS OF REJECTIONS and is made non-final. Any inconvenience the delay may have caused Applicant is deeply regretted.

### *Withdrawn objections/ rejections*

The objection to the specification for failing to identify the sequences on page 15, line 16, and page 43, line 2, has been withdrawn in view of Applicant's amendment to the specification to include the SEQ ID NO: for said sequences.

The rejection under 35 USC 112, 2nd paragraph to claims 26, 31-33, 39 and 41 have been withdrawn in view of Applicant's amendment to the claims and upon further consideration.

### *Claim Rejections - 35 USC § 112*

Claims 20-30, 39-40, 42-46, 52, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 39 are indefinite in the recitation "CDRI1". Since the name "CDRI1" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that

denomination. The name "CDRI1" does not clearly identify the claimed nucleic acid molecules, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Dependent claims 21-30, 40 and 55 do not obviate the rejection, and therefore are included in the rejection.

Amending claims 20 and 39 to recite SEQ ID NO: would obviate this rejection.

***Claim Rejections - 35 USC § 112***

Claims 20-33, 39-40, and 42-46 remain rejected and claims 52 and 54-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to a method of producing transformed plant and plant cells having resistance against bacterial diseases as result of expressing SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2 and plants/plant cells/seed produced by said method. This rejection is repeated for the reasons of record as set forth to the Office action of 08/12/03. Applicant's arguments filed 03/19/04 have been fully considered but are not deemed persuasive.

Applicant argues that the instant invention is enabled throughout the broad scope, taking into account the *In re* Wands factors. Applicant graciously groups his arguments as follows:

1) Applicant argues that the guidance provided on pages 10-11, 16 and 27 to 28 of the instant specification are sufficient to enable one skilled in the art to use fragments of SEQ ID NO: 1 to screen and identify other CDR1 family members from cDNA or genomic libraries from other natural species. Applicant argues that a variety of methods

for producing and screening transgenic plants having increased disease resistance have been disclosed in the specification by actual working examples. Applicant asserts that the quantity of experimentation necessary to practice the claimed invention is routine, given the ample guidance and actual working examples provided in the specification (response, pp. 9-10).

These arguments are not persuasive because Applicant points to no specific methods that allow the specific isolation of the claimed CDR1 genes. The specification only provides general guidance for how to identify and isolate genes but does not provide guidance with respect to the specific hybridization and/or wash or PCR conditions and probes/primers, which would allow successful identification and isolation of other cDNA or genomic clones, or other nucleic acid sequences that encode polypeptides that are functionally related to SEQ ID NO: 2. In addition, Applicant has not provided guidance for functional domains or the region of the full-length sequence of SEQ ID NO: 1 that is necessary to encode a functional polypeptide. In the absence of such guidance, undue trial and error experimentation would be required to screen through the vast number of plant and non-plant cDNA and genomic clones to identify the target genes. Therefore, Applicant's disclosure of a method of producing transgenic plants with increased pathogen resistance with isolated DNA sequences that encode SEQ ID NO: 2 does not support the broad scope of the claims.

2) Applicant argues that the nature of this invention relates to production of transgenic plants, and the prior art teaches a variety of techniques for producing

genetically transformed plants. Therefore, Applicant concludes, that no undue experimentation is required to practice the invention as broadly claimed.

These arguments are not persuasive because the genes that are required for the production of the transgenic plants having enhanced pathogen resistance have not been provided. The state of the art for isolation of cDNA and/or genomic clones of defined function is highly unpredictable. Applicant has isolated a single gene from a single plant species, and shown that overexpression of the gene in Arabidopsis enhanced resistance to bacterial infection. No guidance has been provided with respect to the specific hybridization and/or wash or PCR conditions and probes/primers, which would allow successful identification and isolation of other cDNA or genomic clones, or other nucleic acid sequences that encode polypeptides that are functionally related to SEQ ID NO: 2. Therefore, Applicant's disclosure of a method of producing transgenic plants with increased pathogen resistance with isolated DNA sequences that encode SEQ ID NO: 2 does not support the broad scope of the claims.

3) Applicant asserts the relative skill of those who obtain variants of known genes such as SEQ ID NO: 1, transform plants and screen plants for specific phenotype is high.

This is not persuasive because the claimed invention is not drawn to variants of a known gene, but to a method of producing transgenic plants having increased pathogen resistance by transforming the plant with a nucleic acid encoding a CDR1 polypeptide. A nucleic acid encoding a CDR1 polypeptide has never been isolated before Applicant's invention, and the instant specification fails to provide guidance with respect to the

specific isolation of the target genes from the multitude of various natural species. Therefore, Applicant's disclosure of a method of producing transgenic plants with increased pathogen resistance with isolated DNA sequences that encode SEQ ID NO: 2 does not support the broad scope of the claims.

4) Applicant argues that methods for finding homologs of a known gene such as the disclosed SEQ ID NO: 1, transforming and screening plants are not unpredictable.

This is not persuasive because Applicant has provided no evidence to support such conclusion. Plants as well as other species including animals and microorganisms comprise a battery of host defense mechanisms involving a wide variety of proteins that differ structurally and functionally. Applicant's disclosure of a single gene from a single plant species does not support the broad scope of the claims.

5) With respect to breadth of the claims, Applicant asserts that the breadth of the claimed invention is commensurate in scope with the enabling disclosure (response, pp. 10-12).

This is not persuasive because the claims are broadly drawn to a method of producing transformed plants having enhanced pathogen resistance by using a nucleic acid from any source encoding a CDR1 polypeptide. A CDR1 nucleic acid /polypeptide is defined as nucleic acids or polypeptides having substantial identity to SEQ ID NO: 1 or 2 or conservative variants thereof. In contrast, the specification provides guidance for the nucleic acid of SEQ ID NO: 1 and a method of using said nucleic acid to enhance resistance against bacterial pathogens in plants. The specification fails to provide specific guidance for how to obtain a variant of SEQ ID NO: 1 or 2, much less of other

CDR1 variants. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims, as stated in the last Office action. Therefore, the rejection is maintained.

***Written Description***

Claims 20-33, 39-40, and 42-46 remain rejected and claims 52 and 54-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth to the Office action of 08/12/03. Applicant's arguments filed 03/19/04 have been fully considered but are not deemed persuasive.

Applicant argues that the claimed invention has been sufficiently described, given the described sequence of SEQ ID NO: 1 and nucleic acid sequences encoding SEQ ID NO: 2, and methods for producing genetically transformed plants having increased resistance (response, pp. 12-13).

These arguments are not persuasive because Applicant has not described a representative number of nucleic acid sequences encoding a CDR1 polypeptide required for the production of transgenic plants having increased pathogen resistance. Nor that Applicant describes specific structural elements common to all CDR1 genes that would allow one to predictably determine the identity of the members of the CDR1

genus. A nucleic acid encoding CDR1 polypeptide is described only by its function or the desired result of its use. Consequently, the claimed method that employs said nucleic acid, plants, plant cells, and seed comprising said nucleic acid are not adequately described. The rejection is maintained.

***Claim Rejections - 35 USC § 102***

Claims 20-33, 39-40, and 42-46, 52, and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryals et al (US 5,614, 395). This rejection is repeated for the reasons of record as set forth to the Office action of 08/12/03. Applicant's arguments filed 03/19/04 have been fully considered but are not deemed persuasive.

Applicant argues that Ryals et al do not anticipate the claimed invention because Ryals et al fail to teach all claim limitations.

This is not persuasive. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." Brown v. 3M, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001). See also MPEP § 2131.02.

"The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913,

1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Ryals teach a method of producing transformed plants/plant cells having increased resistance against diseases comprising transforming plant cells with a vector comprising nucleic acid sequences encoding pathogen-related (PR) proteins operably linked to promoters including tissue-specific, constitutive and inducible promoters. Ryals et al also teach regeneration of plants from said transformed plant cells and selection of transgenic plants with enhanced resistance against pathogens including *Psuedomonas syringe* and transgenic plants and seed and plant tissue from said transgenic plants (Examples 109-175). PR proteins provide constitutive disease resistance activity against pathogens including bacterial pathogens (columns 7-8 and 18-20). The reference also teaches transformation by direct gene transfer method including microinjection and use of chemical agent (columns 2 and 3). Resistance to the specific strains of *Psuedomonas syringe* of *Pst and Psm* would be an inherent property of constitutive disease resistance polypeptides. Given the broad definitions of "CDR1" provided in the specification, Ryals teach all claim limitations. Therefore, the rejection is maintained.

***Remarks***

Claims 41 and 53 are free of the prior art because the prior art do not teach or suggest a method of increasing disease resistance in a plant with SEQ ID NO: 1.

Claims 41 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

5/28/04
Mai